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| 09/936,489 | 03/05/2002 | Jean-Richard Neeser | 112843-030 | 7111 |
| 24573 | 7590 | 04/14/2004 | EXAMINER | |
| BELL, BOYD & LLOYD, LLC | | | MARX, IRENE | |
| PO BOX 1135 | | | ART UNIT | |
| CHICAGO, IL 60690-1135 | | | PAPER NUMBER | |

1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,489

Applicant(s)

NEESER ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 3/9/04 is acknowledged. Claims 1-6 and 21-22 are being considered on the merits.

Claims 7-20 are withdrawn from consideration as directed to a non-elected invention.

The rejection under 35 U.S.C 101 is withdrawn in view of applicant's amendment.

The rejection under 35 U.S.C 112, first paragraph, regarding deposit is withdrawn in view of applicant's averments.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guandalini *et al.* (WO 98/06411) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Guandalini does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is

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clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property. See, e.g., Examples and page 6, lines 23-25.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* or species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morelli *et al.* (WO 95/33046) in light of ATCC Catalogue for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Morelli does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* or species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the

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burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pedraglio (EP 861905) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Pedraglio does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* or species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tuomola *et al.* for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Toumola does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property. See, e.g., page 46, col. 1 and Table I, page 48.

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However, the argument that adhesion is better in *E.coli* than in most *Lactobacillus* strains is an argument properly applicable to the specific strain disclosed by applicants and not to any and all strains of *Lactobacillus*. There is nothing in the reference to suggest that no adhesion protection occurs, as alleged by applicants. On the contrary, that adhesion occurs is clearly set forth at page 49. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* or species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-3 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brassart *et al.* (U.S. Patent No. 5,603,930) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Brassart does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing

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non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claims 1-3 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Casas *et al.* (U.S. Patent No. 5837238) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Casas does not disclose that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from the reference that it protects against adhesion of pathogenic bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactobacillus* or species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Guandalini *et al.* (WO 98/06411) or Pedraglio (EP 861905) or Tuomola *et al.* or Brassart *et al.* for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that none of the references discloses that the strain disclosed therein has a protection property against adhesion or invasions of bacterial into intestinal cells. However, it is clear from each of the reference that the strains protect against adhesion of pathogenic

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bacteria, at least by competitive exclusion or by producing antibiotic compounds. This is clearly a protective property.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same species *L. paracasei* as that claimed, likewise shares the property of being a suitable probiotic, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Applicant did not present specific arguments regarding this rejection. Therefore, the rejection is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

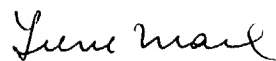
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.

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A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx

Primary Examiner

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